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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/766,138

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John R. Brustad

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12/22/2009

APPLIED MEDICAL RESOURCES CORPORATION

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EXAMINER

WOLLSCHLAGER, JEFFREY MICHAEL

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/766,138	Applicant(s) BRUSTAD ET AL.	
	Examiner JEFFREY WOLLSCHLAGER	Art Unit 1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 1-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Election/Restrictions

Applicant's election of Group II, claims 51-66 in the reply filed on October 8, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 51-66 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 7,534,317. Although the conflicting claims are not identical, they are not patentably distinct from each. Claim 1 of the '317 patent claims a process for manufacturing a kink resistant sheath comprising coating a mandrel with a first layer of plastic material to form an inner tube; placing a braid over the inner tube; placing a spring reinforcement over the braid; and coating the braid with a second layer to form an outer tube of braid-reinforced sheath.

Regarding claim 51, claim 1 of the '317 patent effectively claims all of the elements set forth in claim 51. As such, claim 1 of the '317 patent effectively anticipates claim 51.

As to claims 52-66, claim 1 of the '317 claims the layers of tubing are applied by "coating". In the context of the '317 patent, the term "coating" is understood to include dipping/molding and extrusion processes. As such, one having ordinary skill would have understood the term coating, within the context of the '317 patent, to include dipping/molding and extrusion processes. As such, claim 1 of the '317 effectively renders claims 52-66 anticipated and/or obvious in view of a proper construction of the terms in the '317 patent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 51, 53-57, and 59-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Keith et al. (US 5,888,436).

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Regarding claims 51, 53-57, and 59-61, Keith et al. teach a method of producing a variable stiffness microtubing comprising coating a mandrel (29 or 30) with a first layer of plastic/resin material (13); placing a coiled wire (i.e. spring) reinforcement over the first layer (col. 3, lines 65-col. 4, line 1); and coating the coiled wire/spring reinforced layer with a second layer of resin/plastic (22) to form a reinforced microtube (Figure 1A). The second layer of resin/plastic may be applied in a variety of manners, including extrusion (col. 4, lines 47-64). Further, the mandrel is tapered and each tapered part is understood to provide a separate part in a multiple-part mandrel (Figure 1C). The coiled wire is made of metal.

Claims 51-55, 57 and 59-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Berg et al. (US 5,792,116).

Regarding claims 51-55, 57 and 59-61, Berg et al. teach forming a catheter having a geometrically shaped inner surface (Abstract) wherein a mandrel/core having an outer surface geometrically configured is employed (col. 4, lines 38-52). In the method, the mandrel is coated with a first extruded inner tubular layer, a plurality of strands are wrapped over the first layer, and a second outer tubular is extruded over the strands (col. 4, lines 38-52). Berg et al. teach the plurality of strands are applied in the form of a braid or are helically wrapped (i.e. in a coiled spring configuration) onto the inner layer to form a middle layer (col. 8, lines 15-24).

Claims 51-53, 55-58, 60, 62, 63 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor (US 6,464,632).

Regarding claims 51-53, 55-58, 60, 62, 63 and 65, Taylor teaches a method of producing a flexible liner comprising coating a mandrel (704) with an extruded plastic tubular material; placing a spring reinforcement over the first layer; and coating the spring reinforcement

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with multiple layers by dipping the material in a polymer dissolved in a solvent (Figures 7A-7E; col. 8, lines 47-col. 9, line 40).

Claims 51, 53, 55-58, 62, 63 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Sutton (US 5,472,435).

Regarding claims 51, 53, 55-58, 62, 63 and 65, Sutton teaches a method of producing a drainage catheter comprising coating a mandrel (72) with a polymeric material to form a first layer; applying a spring reinforcement (Figure 11) over the first layer; and dipping the spring reinforced layer in a solvent based solution to form a second layer of the tube (Figure 15; Table D; col. 10, lines 4-col. 11, line 14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 59, 61, 64 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor (US 6,464,632) as applied to claims 51-53, 55-58, 60, 62, 63 and 65 above, and further in view of either of Keith et al. (US 5,888,436) or Chiu et al. (US 6,540,734) or Kolobow (US 5,429,127) or Crowley (US 5,840,031).

As to claims 59, 61, 64 and 66, Taylor teaches the method set forth above but does not teach the mandrel is tapered/has multiple parts. However, each of Keith (Figure 1C), Chiu (Figure 21D), Kolobow (col. 12, lines 32-36), and Crowley (col. 10, lines 60-67) teach that in the art of producing catheters it is known to employ tapered mandrels/mandrels having a variety of sections (i.e. multiple parts).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Taylor and to have employed a mandrel having a tapered part/having a plurality of parts (e.g. a cylindrical part and a tapered part) for the purpose, as suggested by the secondary references, of producing a catheter having a suitable shape for insertion and use.

Claims 59, 61, 64 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton (US 5,472,435), as applied to claims 51, 53, 55-58, 62, 63 and 65 above, and further in view of either of Keith et al. (US 5,888,436) or Chiu et al. (US 6,540,734) or Kolobow (US 5,429,127) or Crowley (US 5,840,031).

As to claims 59, 61, 64 and 66, Sutton teaches the method set forth above but does not teach the mandrel is tapered/has multiple parts. However, each of Keith (Figure 1C), Chiu (Figure 21D), Kolobow (col. 12, lines 32-36), and Crowley (col. 10, lines 60-67) teach that in the art of producing catheters it is known to employ tapered mandrels/mandrels having a variety of sections (i.e. multiple parts).

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Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Sutton and to have employed a mandrel having a tapered part/having a plurality of parts (e.g. a cylindrical part and a tapered part) for the purpose, as suggested by the secondary references, of producing a catheter having a suitable shape for insertion and use.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY WOLLSCHLAGER whose telephone number is (571)272-8937. The examiner can normally be reached on Monday - Thursday 6:45 - 4:15, alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Jeff Wollschlager/
Primary Examiner
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December 22, 2009